PolyPid Announces Last Patient In for Planned Unblinded Interim Analysis in the Ongoing SHIELD II Phase 3 Trial Evaluating D-PLEX for the Prevention of Abdominal Colorectal Surgical Site Infections

Unblinded Interim Analysis to be Conducted During the Current Quarter

Top-line Results Anticipated in First Quarter of 2025

PETACH TIKVA, Israel, Oct. 01, 2024 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today announced that it has enrolled the last patient required in order to conduct the planned unblinded interim analysis in its ongoing SHIELD II Phase 3 trial for D-PLEX$_{100}$ for the prevention of surgical site infections in patients undergoing abdominal colorectal surgery with large incisions. The unblinded interim analysis will be conducted during the current quarter, following the completion of the 30-day follow-up assessment for the last patient. The unblinded interim analysis may allow for early trial conclusion due to positive efficacy, continuation to planned patient recruitment (up to 630 subjects), sample size re-assessment, or futility.

Approximately 430 subjects have been enrolled to date in the SHIELD II Phase 3 trial.

"We are pleased to reach this important milestone in our ongoing SHIELD II Phase 3 trial and look forward to the unblinded interim analysis later this quarter," said Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "Enrollment in the study is accelerating and we remain on track to announce top-line results from SHIELD II in the first quarter of 2025. Importantly, SHIELD II is now nearly three-quarters enrolled to full planned enrollment, which is expected by year-end."

Under the terms of the private placement financing that was closed in January 2024 ("January PIPE"), PolyPid has the potential to secure an additional $18.5 million if the unblinded interim analysis of its SHIELD II Phase 3 trial of D-PLEX$_{100}$ results in the stopping of the trial due to positive efficacy and all warrants are exercised. In addition, under the terms of the private placement financing that was closed in August 2024 ("August PIPE"), PolyPid has the potential to secure an additional $6.1 million if the unblinded interim analysis results in either the stopping of the trial due to positive efficacy, or continuation to planned patient recruitment (up to 630 subjects) and all warrants are exercised. If all the warrants issued in the August PIPE are exercised, the Company would be funded beyond top-line results. If all warrants issued in both January PIPE and August PIPE are exercised, the Company would be funded into 2026.

About SHIELD II

SHIELD II (Surgical site Hospital acquired Infection prEvention with Local D-PLEX) is a

prospective, multinational, randomized, double blind Phase 3 trial designed to assess the efficacy and safety of D-PLEX$_{100}$ administered concomitantly with standard of care ("SoC"), which includes prophylactic systemic antibiotics, compared to SoC alone arm, in the prevention of post abdominal-surgery incisional infection in patients undergoing abdominal colorectal surgeries with large incisions. The primary endpoint of the trial is measured by the proportion of subjects with either a surgical site infection ("SSI") event as determined by a blinded and independent adjudication committee, reintervention, or mortality for any reason within 30 days post-surgery. Patient safety will be monitored for an additional 30 days. The trial enrolls patients in centers in the United States, Europe and Israel.

About D-PLEX$_{100}$

D-PLEX$_{100,}$ PolyPid's lead product candidate, is designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site to prevent SSIs. Following the administration of D-PLEX$_{100}$ into the surgical site, the PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with Active Pharmaceutical Ingredients, enabling a prolonged and continuous release of the broad-spectrum antibiotic doxycycline, resulting in a high local concentration of the drug for a period of 30 days for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX$_{100}$ received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX$_{100}$ is currently in Phase 3 SHIELD II trial for the prevention of surgical site infections in patients undergoing abdominal colorectal surgery with large incisions.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is a late-stage biopharma company aiming to improve surgical outcomes. Through locally administered, controlled, prolonged-release therapeutics, PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with Active Pharmaceutical Ingredients (APIs), enabling precise delivery of drugs at optimal release rates over durations ranging from several days to months. PolyPid's lead product candidate D-PLEX$_{100}$ is in Phase 3 clinical trial for the prevention of abdominal colorectal surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for the treatment of solid tumors, beginning with glioblastoma.

For additional Company information, please visit http://www.polypid.com and follow us on Twitter and LinkedIn.

Forward-looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act and other securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example,

the Company is using forward-looking statements when it discusses the expected timing for top-line results from the SHIELD II trial and of the unblinded interim analysis, that enrollment for the study remains on track, and the Company's expected cash runway and the potential to secure additional funds if all of the warrants issued through the January PIPE and August PIPE are exercised. Forward-looking statements are not historical facts, and are based upon management's current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management's expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed in or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, reference is made to the Company's reports filed from time to time with the Securities and Exchange Commission, including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on March 6, 2024. Forward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking statements to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws. If the Company does update one or more forward-looking statements, no inference should be drawn that the Company will make additional updates with respect thereto or with respect to other forward-looking statements.

References and links to websites have been provided as a convenience, and the information contained on such websites is not incorporated by reference into this press release. PolyPid is not responsible for the contents of third-party websites.

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